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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,604	06/29/2001	Robert A. Hallowitz	BIOT1-11	6514

7590 06/06/2006

Theranostech, Inc.
Attn: Patent Counsel
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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,604	HALLOWITZ ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Applicants are advised that the finality of the last office action has been withdrawn. The amendment filed 15 March, 2005, has been entered. Claims 1-16 are pending in the instant application.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-3, 5-7, 9, and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993). Daniel and colleagues disclose a method for assessing the infectivity status

of a host infected with HIV. This assay involved measuring the number of $CD4^+$ lymphocytes and the number of cell-surface $gp120^+$ lymphocytes as well. Art recognized detection methods employing flow cytometry and appropriate immunological reagents were also disclosed. This teaching does not disclose an assay wherein the measurements of $CD4^+$ lymphocytes and $gp120^+$ lymphocytes were taken independently of one another. However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use any one of a number of art recognized detection formats to assess the number of $CD4^+$ lymphocytes and the number of cell-surface $gp120^+$ lymphocytes to ultimately ascertain the number of $CD4^+$ lymphocytes that are expressing or carrying cell-surface gp120. Absent evidence to the contrary, the skilled artisan could have removed two aliquots and measured each variable independently or measured both variables simultaneously depending upon what type of immunological reagents and apparatuses were available. One of ordinary skill in the art would have also been motivated to determine this ratio on HIV-infected patients at a number of stages and before, during, and after antiviral therapy to ascertain the number of productively infected cells.

Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993) in view of Cummings *et al.* (1999). The significance of the teachings of Daniel and colleagues has been discussed *supra* with respect to claims 11, 12, 14, 15, and 16. This teaching does not disclose art-recognized detection methods employing fluorescence resonance energy transfer (FRET). However, Cummings and associates provide a FRET assay that is useful for measuring viral protein-protein binding interactions. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the FRET assay and reagents provided by Cummings *et al.*

(1999) in the CD4/gp120 assay of Daniel *et al.* (1993). One of ordinary skill in the art would have been motivated to employ a FRET assay because it is a convenient and facile means for detecting binding. Thus, both sufficient motivation and a reasonable expectation of success were present in the prior art.

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over King and Hallowitz (1998) in view of King and Hallowitz (2001). King and Hallowitz (1998) disclose a method for detecting cell-surface gp120 that employs a first anti-gp120 labeled antibody and a second anti-gp120 antibody attached to a magnetic particle. The antibodies are added to an aqueous sample under conditions that facilitate binding, immune complexes are isolated using a magnetic field, and the number of lymphocytes expressing cell-surface gp120 is ascertained. This teaching does not disclose the utilization of a second anti-label antibody that is attached to a magnetic particle. However, King and Hallowitz (2001) provide an assay for the detection of virally infected cells that employs anti-label antibodies attached to magnetic particles. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ the immunological reagents of King and Hallowitz (2001) in the cell-surface gp120 assay of King and Hallowitz (1998) since this would provide a rapid and facile means for detecting virally infected cells. Absent evidence to the contrary, one of ordinary skill in the art would have been motivated to use any one of a number of art-recognized immunological formats to detect the item of interest. Thus, both sufficient motivation and a reasonable expectation of success were present in the prior art.

Claims 11, 12, 14, 15, and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993). Daniel and

colleagues disclose a method for assessing the infectivity status of a host infected with HIV. This assay involved measuring the number of $CD4^+$ lymphocytes and the number of cell-surface $gp120^+$ lymphocytes as well. Art recognized detection methods employing flow cytometry and appropriate immunological reagents were also disclosed. This teaching does not disclose the utilization of this method to assess the infectivity status of patients that are negative by viral co-culture assays. However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to apply this method to a variety of biological samples obtained from HIV^+ or HIV^- negative patients. Concerning patient samples that are initially negative by viral co-culture assays, one of ordinary skill in the art would have been motivated to employ the method of Daniel and colleagues to confirm the negative finding. Thus, sufficient motivation was clearly present to one of ordinary skill in the art.

Claims 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel *et al.* (1993) in view of Cummings *et al.* (1999). The significance of the teachings of Daniel and colleagues has been discussed *supra* with respect to claims 11, 12, 14, 15, and 16. This teaching does not disclose art-recognized detection methods employing fluorescence resonance energy transfer (FRET). However, Cummings and associates provide a FRET assay that is useful for measuring viral protein-protein binding interactions. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the FRET assay and reagents provided by Cummings *et al.* (1999) in the CD4/gp120 assay of Daniel *et al.* (1993). One of ordinary skill in the art would have been motivated to employ a FRET assay because it is a convenient and facile means for detecting binding. Thus, both sufficient motivation and a

reasonable expectation of success were present in the prior art.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

18 May, 2006